

4. Remarks.

A. The amendments made.

The specification has been amended to provide support for the newly added claims 11 and 12, claim 10 has been canceled without prejudice or disclaimer, claims 1-6 and 9 have been amended, and new claims 11 and 12 have been added.

Josephson respectfully requests further examination and reconsideration of claims 1-9, 11, and 12, now pending in the application.

B. The Office action.

The last Office action mailed from the Patent Office on January 8, 2007 has been carefully considered, and indicates that claims 1-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by Chan *et al.*

C. The response.

(1) *The rejection of claims 1-10 under 35 U.S.C. § 102(b) as being anticipated by Chan et al.*

(a) *The amendments made.*

In response to the Examiner's rejection of claims 1-10 under 35 U.S.C. § 102(b) as being anticipated by Chan *et al.*, Josephson has:

- Amended the specification to provide support for newly added claims 11 and 12.
- Canceled claim 10 without prejudice or disclaimer.
- Amended claim 1 to generally include the limitations of canceled claim 10 and to better describe claim 1.
- Added new claims 11 and 12.

(b) 37 CFR § 1.111(c) - claims 1, 11, and 12.

As required by 37 CFR § 1.111(c), each of amended claim 1 and new claims 11 and 12 generally describe the following advantageous distinctive feature that distinguishes over and avoids the prior art:

“said blade end of said shaft extends into said round blade approximately one third to one half said diameter of said round blade.”
[Emphasis added]

(c) *The advantages.*

When the suction round knife of the embodiments of the present invention is designed in accordance with this advantageous distinctive feature, incision, elevation of the canal skin, and suctioning of blood is performed ***at the precise location within the surgical site using only a single instrument and a single hand***, thereby allowing the surgeon to use the other hand for additional instrumentation and work. For example, the tissue of the bony canal wall is ***elevated off while the suction tip is precisely positioned close to the elevator to evacuate blood and maintain visualization***. Once the skin is ***elevated*** off the posterior canal wall down to the ear drum edge, the surgeon delicately ***elevates*** the eardrum edge out of its sulcus. After the flap is ***elevated***, healthy and diseased tissue is ***teased off*** of otologic structures, such as the ear bones, floor of the middle ear, mastoid bone, semicircular canals, cochlea, facial nerve, and other structures.

Previously, during these surgical procedures, the surgeon used a separate suction, a separate elevator, and a separate knife, by rotating these instruments between two hands. The embodiments of the present invention allow the surgeon to have all three instruments in a single instrument and in a single hand, ***with each instrument portion precisely positioned relative to each other and to the operation site***. The suction round knife has a cutting edge, a round surface for elevation, and a suction, all in one. This allows the

surgeon's free hand to use other instrumentation to improve the surgeon's ability to perform these operations.

Surgeries benefitting from the embodiments of the present invention include, but are not limited to, tympanoplasty (repair of eardrum), ossiculoplasty (repair of ear bones), mastoidectomy (remove disease (tumor or infection) from mastoid), cochlear implantation (implant device to provide hearing in deaf patients), congenital ear surgery (create an ear canal), inner ear surgeries for dizziness, facial nerve disorders, and other similar procedures.

As in any surgery, one limitation the surgeon experiences is the use of only his or her two hands. In some types of surgery, the surgeon has the fortune of an assistant to help during his or her work allowing additional hands to hold instrumentation. In microscopic otologic surgery, the surgeon does not have the ability to have an assistant because of the small working area. Therefore, the otologist must rely on instrumentation available and only his or her two hands.

Previously, in the practice of ear surgery, during most procedures the surgeon finds him or herself using one hand to hold a suction to evacuate blood while the other hand cuts, elevates flaps, and removes or repairs disease, tissue or bone.

The hand of the surgeon previously holding the otologic suction is now freed by the embodiments of the present invention to hold an additional instrument while working under the microscope in the ear canal. The surgeon now has three instruments in a single instrument and a single hand, namely, a cutting edge, a round surface for elevation, and a suction, all in one, and ***all precisely positioned relative to each other and to the operation site*** thereby allowing the surgeon's free hand to use other instrumentation to improve the surgeon's ability to perform these operations.

(d) *Not merely a matter of design choice.*

So it has been shown that “said blade end of said shaft extending into said round blade approximately one third to one half said diameter of said round blade”[Emphasis added] is significant, and as such, the courts hold that it is not just a matter of design choice but must be considered in determining patentability.¹

(e) *The reference to Chan et al.*

Turning now to the references, and particularly to Chan *et al.*, Chan *et al.* do not teach “said blade end of said shaft extends into said round blade approximately one third to one half said diameter of said round blade.”[Emphasis added] as generally required by the advantageous distinctive feature of each of amended claim 1 and new claims 11 and 12 discussed above, but rather Chan *et al.* teach that the aperture **88** [relied upon as the distal end of the shaft of amended claim 1] is positioned *less than one third* into the blade **26**, as shown in **FIGURES 5 and 6** of Chan *et al.* [relied upon by the Examiner], and rightfully so, because the aperture **88** is for delivering surgical fluid to the blade and not for providing suction as required by amended claim 1 and newly added claims 11 and 12, as discussed at numerous occurrences throughout Chan *et al.*, for example: “* * * an aperture for delivering said fluid * * *”[Emphasis added].²

Chan *et al.* deliver surgical fluid to the blade to lubricate the tip to minimize irritation of stromal tissue, as discussed at numerous occurrences throughout Chan *et al.*,

¹ For example, *In re Dailey and Eilers*, 149 USPQ 47 (CCPA 1976) (“Appellants have presented no argument which convinces us that the particular configuration of their container is significant or is anything more than one of numerous configurations a person of ordinary skill in the art would find obvious for the purpose of providing mating surfaces in the collapsed container of Matzen. See *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459.”[Emphasis added]).

² Col. 7, lines 30-31 and 56-57 and col. 8, lines 18-19 and 44-45 of Chan *et al.*

for example: “said activating step lubricates said dissecting tip so as to minimize irritation of stromal tissue.”³

Chan *et al.* specifically teach that the number and position of the aperture(s) are *arbitrary*. “As a further example, dissecting tip **14a** may be formed with only one aperture for the delivery of a surgical fluid, or more than two apertures for the delivery of a surgical fluid.”[Emphasis added]⁴ and “* * * apertures **88** and **90** may be located on portions of the blade **26** other than depressions **32** and **34**, if desired.”[Emphasis added]⁵

With this arrangement of Chan *et al.*, the so-called suction portion [the apertures **88** and/or **90**] is *not precisely positioned relative to the other portions and to the operation site* to allow, for example, the tissue of the bony canal wall to be elevated off while the suction tip is *precisely positioned* close to the elevator to evacuate blood and maintain visualization.

(f) 37 CFR § 1.111(c) - claims 6, 7, and 8.

As required by 37 CFR § 1.111(c), claims 6, 7, and 8 describe the following advantageous distinctive features, respectively, that distinguish over and avoid the prior art:

“said bulbous ferrule of said suction interface is disposed around said proximal end of said shaft.”[claim 6][Emphasis added]

“said bulbous ferrule of said suction interface is separate from said proximal end of said shaft”[claim 7][Emphasis added]

“said bulbous ferrule of said suction interface is one-piece with said proximal end of said shaft”[claim 8][Emphasis added]

³ Col. 8, lines 8-9 and lines 54-56 of Chan *et al.*

⁴ Col. 7, lines 5-8 of Chan *et al.*

⁵ Col. 6, lines 22-23 of Chan *et al.*

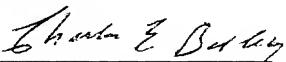
Chan *et al.* are silent as to how the tubing **95** is coupled to the port **92** [relied upon as the suction interface of claims 6, 7, and 8] other than “[p]ort **92** is for fluidly coupling with a reservoir **94**. Such coupling is preferably performed using medical grade silastic tubing **95**.”⁶ Absent such a disclosure, one cannot say that Chan *et al.* teach the advantageous distinctive features of claim 6, 7, and 8.

(g) *The conclusion.*

In view of the amendment made to the specification for providing support for newly added claims 11 and 12, the cancellation of claim 10, the amendment made to claim 1 to generally include the limitations of canceled claim 10 and to better describe claim 1, the addition of new claims 11 and 12, and the arguments presented, Josephson respectfully submits that the Examiner’s grounds for the rejection of claims 1-10 under 35 U.S.C. § 102(b) as being anticipated by Chan *et al.* are no longer applicable and therefore Josephson respectfully requests that the Examiner withdraw this rejection.

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of the rejection is respectfully requested. Allowance of claims 1-9 11, and 12 at an early date is earnestly solicited.

Respectfully,

By: 
CHARLES E. BAXLEY
Attorney of Record
USPTO Reg. 20,149

90 John Street - Suite 309
New York, New York 10038
Tel: (212) 791-7200
Fax: (212) 791-7276
e-mail: ceb@hartbaxley.com

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⁶ Col. 6, lines 31-33 of Chan *et al.*